



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,498	09/02/2003	Randolf Von Oepen	HO-US005378A	2721
22919	7590	11/03/2005		
SHINJYU GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680				
			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/652,498

Applicant(s)

VON OEPEN, RANDOLF

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/720,873.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 1/9/04.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stiffening element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Amendment

The amendment filed 9/2/03 and originally 10/16/01 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the materials claimed for the cover or coating and added to the specification: a biological material, a ceramic, a metallic, or an elastomer were not originally disclosed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8,9,19,20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 2, last paragraph, a polymer is disclosed for the stent cover. There is no other description to provide support for a biological material, a ceramic, a metallic, or an elastomer to be used for the cover or coating.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (6120534) in view of Glastra et al. (EP 0779062). Ruiz discloses (Figs. 2A,2B) a stent configured and arranged to expand with first and second expanding fixing portions **11,12** and a throttle portion **13** coupled to the first and second portions. Ruiz shows (Fig. 3) a catheter **21** having balloons to expand the stent with reduced expandability. Ruiz also shows (Figs. 5B,5C) a liquid impermeable cover **52** on the stent. Ruiz discloses the covering is an elastomeric material, col. 5 lines 47-49. However, Ruiz fails to disclose the expansion is a done by a single balloon. Glastra et al. show (Fig. 6) a stent-catheter arrangement having a balloon **26** with two fully expandable sections **27** and a section of reduced expandability between the expandable sections. It would have been obvious to one of ordinary skill in the art to use a single balloon as taught by Glastra with the stent of Ruiz such that the surgeon has more control in delivering the stent as opposed to manipulating multiple balloons.

Claims 1-3,8,9,13-15 as best understood are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Jaeger (DE 19509464). Glastra et al. show (Fig. 6) a stent-catheter arrangement having a balloon **26** with two fully expandable sections **27** and a section of reduced expandability between the

Art Unit: 3738

expandable sections. However, Glastra does not disclose a liquid impermeable cover over the stent or a stiffening element for forming a reduced expandable section. Jaeger teaches (Fig. 11) a liquid impermeable cover **6** over stent. Jaeger also teaches (Fig. 3) a stiffening element **5** can be used to form a section of reduced expandability. It would have been obvious to one of ordinary skill in the art to use a blood impermeable cover on the stent and a stiffening element as taught by Jaeger with the stent-catheter system of Glastra et al. in order to provide an outer surface that does not allow blood leakage and to provide a throttle portion to increase blood flow to reduce the likelihood of plaque buildup.

Claims 10-12, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra (EP 0779062) in view of Jaeger (DE 19509464) as applied to claims 1-3 above, and further in view of Tower (US 5695498). Glastra in view of Jaeger is explained supra. However, Glastra as modified by Jaeger do not disclose the balloon made of stiffened balloon material. Tower discloses that the balloon is formed of stiffened balloon material and that the reduced expandability section is formed during balloon production, col. 3, lines 21-34. It would have been obvious to one of ordinary skill in the art to use stiffened balloon material and produce this reduce expandability section during balloon production as taught by Tower with the catheter-stent system of Glastra as modified by Jaeger in order to strengthen the balloon such that the chance of the balloon collapsing has been greatly reduced.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

